

REMARKS

Claims 1 - 20 are pending in the case. Claims 1 - 10 have been cancelled. Claims 8 and 9 are withdrawn until allowance of a generic claim. New claims 11 - 20 are added. It is submitted that claims 11 - 17 and 20 are readable on the species in Group I. It is further submitted that claims 1, 11 - 13 are generic claims.

Claims 1, 7 and 10 are objected to because of a number of informalities. Claims 1, 7, and 10 have now been amended to correct the listed informalities.

Claims 1 - 3 and 10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tatum et al. (5,908,397). The Examiner alleges that Tatum et al. discloses in Figures 1 and 5 a device for positioning and supporting legs during casting comprising in claim 1, a member having a planar surface on one side (Figure 1, foot shell 120); operating means provided on the opposite side of the said member (Figure 1, foot positioning supports 100) to said planar surface for operation of the member in the pressure application of the planar surface into contact with at least a part of the foot sole suitably positioned for the purposes (Figure 5) and also for tilting the said member (Figure 5) while the planar surface is in contact with the foot sole for appropriate support and joint or other location of the foot sole during the application and setting of molding material to at least the sole of the foot (column 2, lines 11 - 23).

Regarding claim 2, the Examiner alleges that Tatum et al. shows that the said member carries means for measuring and indicating the angle of tilt of the planar surface when applied to a foot sole (Figure 5, dorsiflexion wedge 130) especially during the application and setting of molding material (column 2, lines 11 - 23).

Regarding claim 3, the Examiner alleges that Tatum shows that the device includes a leg rest (Figure 1, knee support section 70) for placing on a seat or couch and for receiving and positioning a leg of patient seated on the seat or lying on the couch (column 3, lines 49 - 51) whereby the foot of the leg extends forwardly

from the leg rest (Figure 1), the said member being movably mounted from the leg rest for movement to or from an operative contact position of its planar surface with the foot sole and for the tilting of said surface relative thereto (Figure 5).

With respect to claim 10, the Examiner alleges that the method of taking a mold of a foot using the device according to claim 1 with the method steps claimed will be met during the normal operation of the apparatus stated above.

Claim 1 has been amended and claims 11 - 20 have been added to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, claim 1 requires that the device has operating means and that the operating means has means for tilting the member while the planar surface is in contact with the foot sole.

The claims 11 - 20 of the present application have been added to include the feature that the operating means are provided for operation of the member in the pressure application of the planar surface into contact with at least a part of the forefront area of the sole of a foot, and also for tilting said member about a vertical axis in the frontal plane of the foot while the planar surface is in contact with the forefoot part of the foot sole.

The Tatum disclosure does not show or disclose the operating means to have a means for tilting **while** the planar surface of the member is in contact with the sole of the foot of the patient. As stated in Tatum at column 12, line 60, to column 13, line 11, the adjustment to the dorsiflexion wedge 130 is made before the patient is placed on the casting device. Further, the Examiner states that the member as required by claim 1 is shown in Tatum at 100. The member 100 receives foot shells 120 (column 10, lines 32 - 34). Therefore, the member 100 does not have a planar surface which is in contact with the sole of the foot. In Tatum, the foot shells, and not the member 100, are in contact with the soles of the feet. Further, member 100 in Tatum does not have operating means on the opposite side of the member 100 to the planar surface for providing tilting means. The tilting means in Tatum is the dorsiflexion wedge 130 which is positioned between the member 100 and the adjacent foot shell 120 (column 10, lines 65 - 67). Even if the Examiner states that

the member 100 has a planar surface, it is evident that the dorsiflexion wedge 130 is on the same side and NOT the opposite side of the planar surface as required in claims 1, 11, 12, and 13. Therefore, independent claims 1, 11, 12, and 13 are believed allowable.

Further prior art documents referred to in the official action neither teach nor suggest a device which could be used for such purposes. In particular, the prior art documents do not provide evidence of a prior disclosure of a device which can be used for applying pressure to the forefront area of the sole of a foot and tilting the foot about a vertical axis in the frontal plane of the foot during the application and setting of molding material to at least the sole of the foot.

Again, particular reference to Tatum et al., the described device is intended to solve the problems associated with then known devices for preparing orthotics for paraplegics. As stated in column 1, lines 47 to 52, known devices "are often far from optimal largely because the paraplegic's lower extremities are not held in the precise position needed for the casts." Moreover, column 1, lines 53 to 55, state that "Accordingly, a need exists for a casting device which can securely position and support the lower extremities of a paraplegic during the casting process." Hence, the device is clearly intended for stabilizing and securing the position of a patient's legs and feet and to prevent movement thereof, in use. In particular, the device includes ankle restraining straps 110 for holding the ankles of the patient when the casting device is in use and also walls 126, 128, to restrict foot rotation. Hence, the described device does not include means for movement of the planar surface (foot shell 120) about a vertical axis or means for measuring and indicating the angle of angular movement of the planar surface about the vertical axis in use. Further, the specification would not appear to teach towards or suggest such a feature. Indeed, the Tatum et al. device teaches away from the tilting/rotational requirement of the present invention, since any motion in use is prevented.

Claims 4 - 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Tatum et al. in view of Arkhipov et al. (RU-2020891 C1) and Donnery (4,771,548).

The Examiner also alleges that Tatum et al. discloses a device for positioning and supporting legs during casting, as stated above. The Examiner admits that Tatum et al. does not disclose said member wingedly/pivotally mounted from the leg rest for movement about a substantially horizontal/vertical axis and a means provided for measuring and indicating the angle of angular movement of the said member and its planar surface about the substantially vertical axis.

With respect to said member wingedly/pivotally mounted from the leg rest for movement about a substantially horizontal/vertical axis, the Examiner alleges that Arkhipov et al. teaches said member wingedly/pivotally mounted from the leg rest (pivots 7) for movement about a substantially horizontal/vertical axis (the Figure). The Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device for positioning and supporting legs during casting of Tatum et al. so as to include said member wingedly/pivotally mounted from the leg rest for movement about a substantially horizontal/vertical axis so as to provide a greater enhancement in mobility during use of the device.

The Examiner further states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device for positioning and supporting legs during casting of Tatum et al. so as to include a means provided for measuring and indicating the angle of angular movement of the said member and its planar surface about the substantially vertical axis as taught by Donnery so as to provide a means for facilitating objection and consistent assessment of angular movement.

The Applicant had an English translation of the Arkhipov citation prepared, copy attached, which shows that the apparatus is clearly used for stabilizing the 'leg' following a fracture, rather than for corrective rotational/tilting treatment of a foot. Indeed, the Arkhipov et al. device includes a foot holder 5 (see Figure 3) in the form of a stirrup, for resting the foot during the application of plaster following fracture. Although the stirrup would appear to be adjustable at 6 about a vertical axis, this movement is intended to facilitate positioning of the foot holder 5 relative

to the rest of the device in a suitable configuration prior to positioning of a patient's leg and foot on the device. The device is intended to be used in post tibia fracture treatment. Therefore, there would be no requirement for adjustability of the foot holder about any axis, especially a vertical axis, during the use, since movement of the foot would open or close the tibia fracture, causing discomfort and possible incorrect healing of the fracture zone. Since movement of the foot holder 5 in use is clearly undesirable, the Arkhipov device teaches away from the tilting/rotational requirement of the present invention. Indeed, the description states that the hinges of the foot holder and the tibia fixing unit restrict rotational movement of the tibia (and therefore the foot) in use.

Furthermore, the adjustability of the foot holder 5, in use, would not be effective in tilting the frontal plane of a foot positioned on the Arkhipov device. The axis of the foot holder 5 is angled directly beneath the ankle joint (see Figure 1) and, therefore, will not allow movement of the planar surface of the foot in the frontal plane, since the movement in the frontal plane of the foot comes from the joint below the ankle joint (the subtalar joint). Also, the foot holder does not provide a means for plantigrade contact of the sole of the foot, in particular the forefoot area, as required in the production of accurate foot and ankle/foot orthotics.

The Arkhipov device could not be used for rotational treatment, measurement or assessment of a foot during application and hardening of a plaster mold, and such use is neither taught nor suggested. Since Tatum et al. and Arkhipov et al. both teach away from the present invention, it is respectfully submitted that it would not be obvious for a skilled addressee to combine the features of the disclosures to arrive at the features of the present invention as set out in the amended claims. In this respect, claims 1, 11, 12 and 13 are allowable and provide generic claims which are both novel and inventive and which covers all of the embodiments of the invention set out in Figures 1 to 13.

Claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Tatum et al. in view of Fullen et al. (5,678,448). The features in Fullen do not overcome the deficiencies in the Tatum disclosure with respect to amended claim 1

and new claims 11, 12, and 13.

The Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the device for positioning and supporting legs during casting of Tatum et al. so as to include operating means for measuring and indicating the pressure of application of said member when the planar surface thereof is in contact with the foot sole, as taught by Fullen et al., so as to provide a compact force measurement system for minimizing restriction of movement by the user during use of the device. This amendment should place this case in condition for passing to issue. Such action is respectfully requested.

Respectfully submitted,  
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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the claims:**

Please amend claims 1, 7, and 10 as follows:

1. (Amended) A device for use in taking a mould from a foot comprises: [-]

(a) a member having a planar surface on one side, and

(b) operating means provided on the opposite side of the said member to said planar surface for operation of the member in the pressure application of the planar surface into contact with at least a part of the sole of [a] the foot suitably positioned [for the purposes and also] therein, said operating means further providing means for tilting the [said] member while the [planar] planar surface is in contact with the foot sole for appropriate support and joint or other location of the foot sole during the application and setting of moulding material to at least the sole of the foot.

7. (Amended) A device according to claim 1 wherein the operating means is arranged to also operate means for measuring and indicating the pressure of application of the said member when the planar surface thereof is in contact with [a] the foot sole.

10. (Amended) Method of taking a mould of a foot using a device according to claim 1 comprising: [-]

[1.](a) applying the planar surface of the said member by pressure application to at least part of the sole of a foot suitably positioned for the purpose;

[2.](b) tilting the said member while its planar surface is in contact with the foot sole for appropriate support and joint or other location of the foot sole;

[3.](c) applying moulding material to at least the foot sole while so supported;

[4.](d) allowing the moulding material to set while the foot sole is so supported; and

[5.](e) withdrawing the planar surface from contact with the foot sole and effecting removal of the set moulding material from the foot.

Please add new claims 11 - 20 as follows:

11. (New) A device for use in taking a mold from a foot comprising:

a member having a planar surface on one side; and

operating means provided on the opposite side of said member to said planar surface for operation of said member in the pressure application of the planar surface into contact with at least a part of a forefront area of a sole of the foot suitably positioned for the purposes and also for tilting said member about a vertical axis in a frontal plane of the foot while the planar surface is in contact with the forefoot part of the foot sole for appropriate support and joint or other location of the sole of the foot during the application and setting of molding material to at least the sole of the foot.

12. (New) A device for use in taking a mold from a foot of a patient comprising:

a leg rest;

a member having a planar surface on one side;

operating means wherein said leg rest is provided for placing on a seat or couch and for receiving and positioning a lower leg of the patient seated on the seat or lying on the couch whereby the foot of the leg extends forwardly from the leg rest;

said member is connected to the leg rest for articulated movement relative thereto; and

said operating means are provided on the opposite side of said member to said planar surface, for operation of the member in the pressure application of the planar surface into contact with at least a part of a forefoot area of a sole of the foot suitably positioned for the purposes and also for tilting the member



about a vertical axis in a frontal plane of the foot while the planar surface is in contact with the forefoot part of the sole of the foot for appropriate support and joint or other location of the sole of the foot during the application and setting of molding material to at least the sole of the foot.

13. (New) A device for use in taking a mold from a foot comprising:

a member having a planar surface on one side;

operating means provided on the opposite side of the said member to said planar surface for operation of the member in the pressure application of the planar surface into contact with at least a part of a forefoot area of a sole of the foot suitably positioned for the purposes and also for tilting said member while the planar surface is in contact with a forefoot area of the sole of the foot for appropriate support and joint or other location of the sole of the foot during the application and setting of molding material to at least the sole of the foot;

a leg rest for placing on a seat or couch and for receiving and positioning a leg of patient seated on the seat or lying on the couch whereby the foot of the leg extends forwardly from the leg rest;

wherein said member is movably mounted from the leg rest for movement to or from an operative contact position of its planar surface with the sole of the foot and for the tilting of said surface relative thereto; and

wherein the said member is pivotally mounted from the leg rest for angular movement about a substantially vertical axis for angular side tilting of its planar surface relative to the sole of the foot when in contact therewith.

14. (New) A device according to claim 13 wherein the said member carries means for measuring and indicating the angle of tilt of the planar surface when applied to a sole of the foot especially during the application and setting of molding material.

15. (New) A device according to claim 13 wherein said member is hingedly mounted from the leg rest for movement about a substantially horizontal axis or about more than one such axes for movement to or from an operative contact position of its planar surface with the sole of the foot and for tilting of said surface relative thereto about the or each horizontal hinging axis.

16. (New) A device according to claim 13 wherein means is provided for measuring and indicating the angle of angular movement of the said member and its planar surface about the substantially vertical axis.

17. (New) A device according to claim 13 wherein the operating means is arranged to also operate means for measuring and indicating the pressure of application, of the said member when the planar surface thereof is in contact with a foot sole.

18. (New) A device according to claim 13 wherein the said member is provided at its planar surface with depressible means for contact by at least one metatarsal point of the sole of the foot whereby on lift off of the metatarsal point from said depressible means the depressible means is caused to operate switch means controlling indication means for indicating. that lift off has taken place.

19. (New) A device, according to claim 18 whereon the depressible means comprises at least one spring loaded button and cooperating switch.

20. (New) Method of taking a mold of a foot using a device according to claim 1 comprising the steps of:

applying the planar surface of the said member by pressure application to at least part of the sole of a foot suitably positioned for the purpose;

tilting the said member while its planar surface is in contact with the sole of the foot for appropriate support and joint or other location of the foot sole;

applying molding material to at least the sole of the foot while so supported;

allowing the molding material to set while the sole of the foot is so supported; and

withdrawing the planar surface from contact with the sole of the foot and effecting removal of the set molding material from the foot.

Apparatus for Repositioning and securing broken bones consisting of two pairs of clamps; repositioning unit; cinematographic connection with clamps, spoke holders with spokes.

The repositioning unit works using a cogged-worm reducing gear

The three-point bracket and plates are positioned perpendicular to the platforms.

The disks providing the lever mechanism are connected to both the mobile and non-mobile clamps and joined to the body of the reducing gear.

The different possibilities of repositioning can be attained by moving the three platforms, the three-point bracket and by the rotation of the end lever mechanism.

The limitations of this design are:

The degree of accuracy in repositioning the tibia is not high enough.

The use of this design is well documented with regard to the surgical treatment of fractures of the tibia. The apparatus maintains a link to the distractor. The length of the telescopic rod is adjustable and is regulated by the height of the posts. The cradle is fixed onto one of the posts, the foot-holder onto the other and the tibia-fixing unit is attached to the third post.

Suggestions for overcoming limitations: The technical verdict is as follows:

The degree of accuracy in repositioning the tibia is not high enough.

There is a probability that the surface of the apparatus may become contaminated by harmful bacteria. The surface of the apparatus requires regular sterilisation and failure to maintain this may lead to complications such as the tearing of soft tissues as well as an overall increase in the healing time. Such complications are a particular risk during treatment with open fractures. The aim of the invention is to increase the accuracy of repositioning; decrease healing time; by controlling micro-movement of the fractured bones and excluding irregular repositioning of fractures.

It is also important to guarantee unfavourable conditions for the growth of bacteria on the surface of the apparatus and in its joints.

Fig 1 shows a general view of the apparatus; Fig 2- the tibia-fixing unit; fig 3- foot holder; fig 4- space for X-ray film within the tibia -fixing unit.

The apparatus consists of front 1 and back 2 support posts these are joined by means of a telescopic rod 3 with folding supports 4 ( The plane of movement of the support is indicated by the arrows A)

The front support post 1 consists of the foot holder 5, this is attached to the posts by means of a spherical hinge 6 and with rod 3 - by a flat hinge 7 ( the plane of movement of the flat hinge is shown in fig 1 and indicated by the arrows B) Flat hinge 6

The length of rod 3 can be adjusted by the two screws with flywheel 11.

The tibia fixing unit ( see fig 2) has support 12, catch 13 and bracket 14, the rod 15 is attached to the end of this, and clip 16 attached to rod 3 using a cut clutch 17 allowing for length-ways adjustability of the rod 3. Supports 18, rods 15 and posts 12 are designed to allow the accommodation of cassette 19 and X-ray film ( see fig 4)

The surface of the hinge element and head are coated with a covering containing a surface-active protection substance ( Ephrenes)

The surface of the apparatus itself is coated with a covering containing Fluorine (Ephrenes)

The size of the foot holder is adjustable using an elastic material of type V. The tibia-fixing unit is mobile in two perpendicular planes and has rotational properties. Control of the repositioning process is secured by the use of X-ray film attached to the supports 18. The exterior surface of the apparatus is covered with a substance which impedes the growth of harmful bacteria. This practice allows the apparatus to be used in the field. Reduction in size and dimension means that the apparatus is more mobile and can easily be transported and used in the field.

The use of a surface-active protective substance in the construction of the hinges and joints protects the moving parts from corrosion. The stability of the materials used in the apparatus when in contact with water, oil, lubricant organic dilution, alkaline, acid and other chemical substances allows the uses of various preparations and substances during the sterilisation process of the apparatus' surface and allows for exploitation in many different conditions. The coating of the apparatus' surface with an active protective substance leads to an increase in the strength by 5-6 times as compared to that of the control surface.

The use of these coverings decreases the need for cleansing treatments of the surface and hinges of the apparatus.

The residue of these treatments does not impede the work of the hinges. (Composition high molecular structure of fluorine containing substance MGO Tekhnohim NPO GIPX 1990: The government body PE 2-68-03-88 HPO "GIPKH" 1988).

The apparatus for repositioning the tibia is used in the following way:

Firstly the length and height of the mechanisms 10 and 11 must be set in accordance with the size of the final apparatus indicated.

The point of fracture must then be anaesthetised and then the spoke may be attached to the heel bone. Spoke 20. The spoke is attached to the heel bone, secured by the strap and fixed to the apparatus. Depending on the position of the fracture of the tibia the distractor is used using the telescopic rods.

The hinges of the foot holder and the tibia-fixing unit hold up rotational movement of the tibia.

Repositioning of the tibia is carried out by the movement of the bracket into the vertical plane and the guiding rod with support into the horizontal plane. The actual fixing of the tibia into the correct position can take place after an X-ray has been taken showing the exact position of the tibia. An additional repositioning is allowed in cases when the degree of accuracy of repositioning was insufficient. The construction is permanently fixed onto the tibia after the final repositioning has taken place.

Analysis has shown that the apparatus allows the repositioning of the tibia to be carried out to a great degree of accuracy both within a hospital environment and in the field. The apparatus is simple to manufacture and operate and offers widespread use for those involved in practical treatment.

Invention Formula

The apparatus for repositioning the tibia maintains a link with the distractor by way of telescopic rod with adjustable length and posts with adjustable height. The cradle is attached to one of these and the angle of tilt can be adjusted in the direction of the distractor. The foot holder is attached to the other post and allows rotation relative to the support. The tibia-fixing unit is attached to the third post. This differs in that the tibia-fixing unit is accommodated on the post and has the option of movement of the bracket upon which the rod is fixed using the strap and support. The free end of the post and the post holding the tibia-fixing unit allows for movement and rotation.

2. Apparatus no.1 differs in that the supports with the foot holder and cradle are attached to the distractor hinge and have adjustable positions to the plane of the posts.

3. The apparatus no.1 differs in that the cradle uses a strap with buckles.

4. The apparatus no. 1 differs in that the foot holder is made of elastic material of "v-model type."

5. The apparatus differs in that its surface is coated with a covering of surface-active protective substance, "ephrenes class. "

6. The apparatus no 1 differs in that the working hinges are coated with a layer of surface-active protective substance, "ephrenes class "